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JUL 30 2007 K070515

Section 4: 510(k) Summary

The assigned 510(k) number is: K070515

Company:	Cordatec n.v. Kwikaard 104 B-2980 Zoersel Belgium Telephone: 32 3 380 15 81 Fax: 32 3 380 15 90
Contact:	Barbara DeBiase
Date Prepared:	June 25, 2007
Proprietary Names:	A-View® Basic and A-View Plus
Classification Name:	Accessory to a Diagnostic Ultrasound Transducer
Common Name:	Tracheal Balloon Catheter
Classification:	21 CFR 892.1570, Class II, Product Code MUI
Predicate Device:	• Saline based upon its pre-amendment status in conjunction with ultrasonic water baths; • K052021 V5Ms Transesophageal Transducer and MPT7 Multiplane Transesophageal Transducer by Siemens Medical Solutions USA Inc.; • K994373 HDI 1500/SA 8800 Ultrasound System with Multiplane by Advanced Technology Laboratories Inc.; and • K052517 Site-Rite 5 Ultrasound System by C.R. Bard Inc.
Device Description:	A-View Basic consists of only the catheter itself. The A-View catheter has three tubes connected by a Y-connector of which one holds a distal, large balloon, one holds a small, pilot balloon and the third holds a stop cock with two standard female luer connections. Both balloons are clear and colorless. On the main shaft a distance mark indicating 24 cm from the closest balloon shoulder is pointed out. A-View Plus consists of the catheter plus a standard 50 ml syringe with luer connector and a swivel Y-connector.

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Intended Use:	A-View® catheters are intended for use in conjunction with TEE investigation of the upper mediastinum in anaesthetised patients. They allow visibility of the distal ascending aorta by TEE and permit the condition of the ascending aorta to be evaluated before surgery. A-View Catheters are limited for use in adult patients.
Performance Data	Data is contained within this 510(k) demonstrating A-View catheters meet the requirements of ISO 14971 (Risk Management), ISO 10993 (Biocompatibility), EN 550 (Sterilization), and EN 868 (Packaging).
Conclusion:	A-View catheters are substantially equivalent in function, materials and intended use to the above referenced predicate devices.

CORDATEC N.V. • KWIKAARD 104 • B-2980 • ZOERSEL (BELGIUM)
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2007

Cordatec N.V.
C/O Ms. Barbara DeBiase
Regulatory Consultant
1467 Vigilante Avenue
Bailey, Colorado 80421

Re: K070515
Trade/Device Name: A-View® Basic and Plus Catheters
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: II
Product Code: ITX
Dated: July 23, 2007
Received: July 24, 2007

Dear Ms. DeBiase:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070515

Device Name: A-View® Basic and Plus Catheters

Indications for Use:

A-View Catheters are intended for use in conjunction with TEE investigation of the upper mediastinum in anaesthetised patients. They allow visibility of the distal ascending aorta by TEE and permit the condition of the ascending aorta to be evaluated before surgery. A-View Catheters are limited for use in adult patients.

Prescription Use ___XX____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(acting DC.)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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